K123868

5. 510(k) SUMMARY

December 14, 2012

JAN 0 8 2013

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Gary Chumbimune
Manager, Global Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: (224) 270-3312
Fax: (224) 270-4119

DEVICE NAME:

Trade name:
Interlink System

Table 5-1.
Representative Product Codes for the Interlink System

Code number	Name
2C9292	INTERLINK System Lever Lock Cannula with Check Valve
2H7452	Non-DEHP Secondary Medication Set with DUO-VENT Spike
2C6402	INTERLINK System Solution Set
2H6537	Non-DEHP CONTINU-FLO Solution Set
1C8533	INTERLINK System Vented CONTINU-FLO Solution Set
1C8669	INTERLINK System CONTINU-FLO Solution Set

Common name: Interlink Lever Lock Cannula, Interlink Solution Sets, Interlink Secondary Medication Sets, and Interlink Continu-Flo Sets.

Classification name: IV Administration Set: 21 CFR 880.5440

PREDICATE DEVICE:

Table 5-2.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
SafeSite ™ Injection Site and SafeSite ™ Blunt Cannula	Baxter Healthcare	K883638	September 23, 1988

DESCRIPTION OF THE DEVICE:

The proposed devices, which are the subject of this Special 510(k) Premarket Notification, consist of the Interlink Lever Lock Cannula, Interlink Solution Sets, Interlink Secondary Medication Sets, and Interlink CONTINU-FLO Sets. They are single use disposable devices intended for use with a vascular device for continuous or intermittent fluid administration. These devices are the same as the current marketed devices, previously cleared under 510(k) premarket notifications K883638 (cleared on September 23, 1988), K925126 (cleared on June 18, 1993), and K940697 (cleared on August 30, 1994).

The Interlink Lever Lock Cannula is intended to function exclusively with the Interlink Injection Site as a fluid path injection device. It has a female Luer that allows the connection of a syringe or the distal end of an Interlink Secondary Medication Set to an Interlink injection site of an Interlink solution set or an Interlink CONTINU-FLO set.

The Interlink Solution Sets, Interlink Secondary Medication Sets, and Interlink CONTINU-FLO Sets are used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. They can be used for gravity or pump infusion of I.V. fluids. Interlink CONTINU-FLO Sets contain the Interlink Injection Site that can be used for the administration of secondary medication. They also contain a check valve which prevents blackflow of solution from the secondary medication container into the primary container during the administration of secondary medication. Interlink Secondary Medication Sets are used in conjunction with Interlink CONTINU-FLO sets to administer intermittent fluids to the patient.

The basis for this premarket notification is a modification to the Interlink Lever Lock Cannula, which is an integral part of the Interlink System. The modification consists of replacing the

solvent carrier used in the silicone lubrication process of the Interlink Lever Lock Cannula. The product labels are also being updated to add the indications for use statement of the device and clarify their use to comply with Baxter's labeling standards.

STATEMENT OF INTENDED USE:

For the administration of fluids from a container to the patient through a vascular access device. The Interlink Lever Lock Cannula is indicated to function exclusively with the Interlink Injection Site as a fluid path injection device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices consist of the Interlink Lever Lock Cannula, Interlink Solution Sets, Interlink Secondary Medication Sets, and Interlink CONTINU-FLO Sets. These devices are the same as the current marketed devices, previously cleared under 510(k) premarket notifications K883638 (cleared on September 23, 1988), K925126 (cleared on June 18, 1993), and K940697 (cleared on August 30, 1994). A minor modification will be made to the silicone lubrication process of the Interlink Lever Lock Cannula. The intended use, the basic design, function and the materials for the proposed device are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. Below is a summary of the performance assessment of the Interlink Lever Lock Cannula conducted to show that it is suitable for its intended use:

- Insertion force test
- Removal force test
- Tip protector removal force test
- Lever arm maximum activation integrity test
- ISO Luer tests on female Luer lock connector
- Lipid resistance test
- Lever lock flow test

CONCLUSION:

The proposed devices are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 8, 2013

Mr. Gary Chumbimune
Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
32650 North Wilson Road
ROUND LAKE IL 60073

Re: K123868
Trade/Device Name: Interlink System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 14, 2012
Received: December 17, 2012

Dear Mr. Chumbimune:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

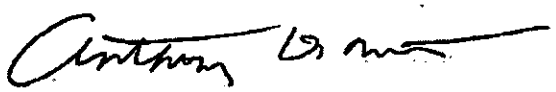
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123868

Device Name:

Interlink System

Indications for Use:

For the administration of fluids from a container to the patient through a vascular access device. The Interlink Lever Lock Cannula is indicated to function exclusively with the Interlink Injection Site as a fluid path injection device.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2013.01.09 10:40:59 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number:_____